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| 10/038,640 | 01/04/2002 | Jonathan S. Stinson | 23,369-110 | 9194 |

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PATENT DEPARTMENT
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EXAMINER

PANTUCK, BRADFORD C

ART UNIT PAPER NUMBER

3731

DATE MAILED: 08/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/038,640

Applicant(s)

STINSON, JONATHAN S.

Examiner

Bradford C Pantuck

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05/17/2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-51 is/are pending in the application.
- 4a) Of the above claim(s) 9, 11-13, 16, 18-24, and 31-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8, 10, 14-15, 17, and 25-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of 1-8, 10, 14-15, 17-18, and 25-30 in the reply filed on May 13, 2004 is acknowledged.
2. Upon further review claim 18 is withdrawn as being directed to a non-elected species. Claims 1-8, 10, 14-15, 17, and 25-30 are all directed to Figure 4 (elected in Response dated February 18, 2004), but claim 18 is directed to another (non-elected) species, such as Figure 5. In conclusion, claims *1-8, 10, 14-15, 17, and 25-30 have been examined.*

Content of Specification

3. The specification is objected to as failing to describe each and every drawing. Specifically, Applicant neglects to refer to Fig. 4a in the "In the Drawings" section on pages 8 and 9 of the specification: Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74 is required.

Drawings

4. Figure 2 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawing sheets are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the

changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 1-4, 8, 14, 15, 17, 25-27 and 29 are rejected under 35 U.S.C. 102(e) as

being anticipated by Publication No. US 2001/0041930 A1 to Globerman et al.

Regarding Claims 1-3 and 27, and Globerman discloses a body insertable prosthesis, including strand (15/13/11/9/7/5) [see Fig. 2] that extends the length of the stent. The strand is one strut of each discrete section. There are six discreet tubular sections of stent (1) shown in Figure 2. Each tubular segment (15/13/11/9/7/5) is separated from the respective adjacent segment by annular members (19) {paragraphs [0013] and [0014]}.

The various tubular segments (15/13/11/9/7/5) have different stiffness levels and radial force levels {paragraphs [0009] and [0013]}. Figure 1f shows how the bending moment varies along the longitudinal axis of the stent. Accordingly, the radial force

level imparted by the stent in the longitudinal axis will vary proportional to the bending moment.

Regarding a “third axial stiffness level is outside of a range of axial stiffness levels bound by the first and second axial stiffness levels,” as set forth at the end of claim 1, Globerman discloses such a configuration. For example, first tubular section 5 and second tubular section 15 will have substantially the same stiffness level (“smaller and softer” = not very stiff) and tubular section 11 has a stiffness level (“very hard” = quite stiff) outside the range (zero) bounded by the first and second tubular sections.

6. Regarding Claim 4, tubular sections 11 and 7 have higher stiffness levels than tubular section 15 [Fig. 2].
7. Regarding Claims 8, tubular section 11, being that it is harder, will supply a higher radial force level, which is outside the range of the radial force level of sections 15 and 5. In other words, sections 15 and 5 will not be able to apply as high a radial force level as section 11.
8. Regarding Claim 14, Globerman’s stent has alternating segments of low and high stiffness. Section 15 has low stiffness, section 11 has high stiffness, and section 5 (again) has low stiffness. This is an alternating series.
9. Regarding Claim 15 Globerman’s Figure 2 discloses such an arrangement: One can think of three distinct sections of the stent: Section 13/15, section 11/9, and section 7/5. In this arrangement each section is comprised to two tubular sections. Section 13/15 has a relatively low (average) stiffness, section 11/9 has a relatively

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high (average) stiffness, section 7/5 has a relatively low (average) stiffness.

Paragraph [0016] discloses a stent with a total length of 10 cm, meaning that each section will have a length of 3.33 cm.

10. Regarding Claim 17, the first, second, and third segments have substantially the same nominal diameters, which is approximately equal to the outer diameter of catheter 3 {paragraph [0013]; Fig. 2}.
 11. Regarding Claim 25, discloses a stent having a prosthesis insertable into a natural body lumen with natural curvature. His stent has at least three alternating tubular segments, each having a relatively high stiffness level. Second tubular sections 15 and 5 have an axial stiffness lower than first tubular section 11. If a segment is less axially stiff it will *always* more readily conform to the curvature of a body lumen (or any other lumen) in which the tubular prosthesis is deployed. Globerman discloses that his stent has “variable flexibility...along its length” {Paragraph [0009]}.
 12. Regarding Claim 26, Applicant should note that *three segments are defined in claim 25 as a sequence*. Both of the second tubular segments (15 and 5) have the same axial stiffness and the first tubular segment (11) has an axial stiffness.
 13. Regarding Claim 29, Globerman’s first tubular wall segments 11 and 7 have higher radial force levels than second wall segment 15.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
14. Claims 25 and 28-30 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,836,966 to St. Germain. Regarding Claims 25 and 28-30, St. Germain discloses a stent having at least three alternating sections. With reference to

Figure 7, St. Germain discloses a stent with second tubular wall segments (84) alternating with first tubular segment (86). Column 3, lines 66 and 67 explain that the force curve for the stent of Fig. 7 is shown in Figure 5. Thus, the stent of Fig. 7 has alternating segments of high and low *radial* stiffness. Sections 1 (86) have lower axial stiffness and section 2 (84) has higher axial stiffness. On page 3 lines 1-2 of Applicant's specification, it is asserted, "axial flexibility can be improved by increasing the strand crossing angle of the helices." From this statement, it is evident that in Figure 7 of St. Germain's patent shows a stent with sections (86) having higher *axial* stiffness than central section (84). In other words, the strands of sections (86) have a lower crossing angle, and the strands in section (84) have a higher crossing angle. Applicant should note that St. Germain does not speak about the concept of axial stiffness per se, but *shows a stent with the structure that Applicant claims*. Thus, St. Germain has anticipated Applicant's invention.

15. Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 880 948 A1 to Thompson, et al. Thompson discloses in Figures 10-12 and in Column 10 line 38 to Column 11 line 12 a stent graft having three parts: 730, 732, and 734. Component 732 is an essentially an opening in the graft to allow it to be placed adjacent a branch vessel, allowing blood to pass from the trunk to the branch [see Fig. 10]. (730, 732, and 734); two of which will have the same stiffness (730 and 734) and one (732) which will have a stiffness level outside that of the other two because it has fewer filaments [see Column 7, lines 44-48].

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. Claims 6, 7, and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 880 948 A1 to Thompson, et al. in view of U.S. Patent No. 5,836,966 to St. Germain. Thompson discloses a plurality of discrete tubular segments as set forth in claim 1. Thompson discloses putting his stent/graft in a stenosed junction of the internal and external carotid arteries [Column 10, lines 20-37; Fig. 10]. Thompson fails to disclose differentiation in crossing angles between the discrete segments. However, St. Germain discloses a stent having various stiffness levels due to differentiation in crossing angle within the three sections of the stent [Fig. 7; Column 3 line 66 to Column 4 line 23]. St. Germain teaches that prior art stents with uniform radial force along the longitudinal axis (such as Thompson's) are deficient in areas of stenosis within a blood vessel because the stenosed region needs more force than the healthy part of an artery [Column 1, lines 43-63]. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to replace the two end portions (730 and 734) of Thompson's device with the stent of St. Germain (as shown in Fig. 7) in order to provide sufficient force to hold the heavily stenosed regions adjacent the opening of the external carotid artery open, while providing just

the right amount of force to the healthy, non-stenosed regions of the artery [Column 1, lines 47-63], as taught by St. Germain.

17. Regarding Claims 6, 7, and 10 the modified Thompson stent now remains with the central section 732 connected at both ends to the stent disclosed by St. Germain in Figure 7. Thus, the stent has three discreet tubular sections, each having a different crossing angle and a different stiffness level.

Conclusion

18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Patent No. 5,064,435 to Porter

U.S. Patent No. 6,371,982 B2 to Berg et al.

U.S. Patent No. 5,824,040 to Cox et al.

U.S. Patent No. 5,938,697 to Killion et al.

U.S. Patent No. 6,409,750 to Hyodoh et al.

U.S. Patent No. 5,575,818 to Pinchuk

U.S. Patent No. 5,449,373 to Pinchasik et al.

Publication No. 2002/0007210 A1 to Chouinard et al.

U.S. Patent No. 6,685,738 B2 to Chouinard et al.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradford C Pantuck whose telephone number is (703) 305-8621. The examiner can normally be reached on M-F 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaver or McDermott can be reached on (703) 308-0858. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BCP
BCP
August 4, 2004

Kevin T. Truong
KEVIN T. TRUONG
PRIMARY EXAMINER

8/4/04